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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/719,415 | 11/21/2003 | Dusan Pavcnik | PA-5360-RFB | 3409 |
| 9896 7590 07/10/2009 COOK GROUP PATENT OFFICE P.O. BOX 2269 BLOOMINGTON, IN 47402 | | | | |
| EXAMINER | | | | |
| PRONE, CHRISTOPHER D | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3738 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,415

Applicant(s)

PAVCHNIK ET AL.

Examiner

CHRISTOPHER D. PRONE

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-22 is/are pending in the application.
- 4a) Of the above claim(s) 3, 13, 15 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-12, 14, 16-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-11, 14, 17, 18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love United States Patent 5,865,723 in view of Robinson et al United States Patent 5,891,193 and Pinchuk United States Patent 5,628,788.

Love discloses the invention substantially as claimed comprising expandable first inner stent 16, expandable second outer stent 14, and a tissue graft layer 12 comprising an extra cellular matrix material collagen disposed on the first stent and under the second. Love also discloses that the stent may comprise a plurality of circumferential segments and a plurality of tie bars shown in figure 9. In regards to claims 17, figure 2 of Love shows that the outside diameter of the first stent is greater than the inside diameter of the second stent. In regards to claim 18 Love further discloses that the first and second stents have equivalent inside and outside diameters (7:25-37). Love further discloses that the graft may be held in place by compression forces between the outer stent and the inner stent (8:17-30) and that it may be utilized without any additional attachments such as adhesives or sutures (7:10-15).

However, Love does not disclose that the distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of the graft or that the inner stent expands to provide the compressive force,

Robinson teaches the use of a tubular implant comprising a tissue graft 20 and an inner expandable stent member having anchors that extend beyond the grafts distal and proximal ends in the same field of endeavor for the purpose of securely anchoring the distal and proximal ends of the implant to the operation site.

Pinchuk teaches use of an implant comprising a stent and a graft that retains their positioning during and after implantation by compressive forces provided by stents made from expandable nitinol in the same field of endeavor for the purpose of providing an implant that expands to the exact shape of the implantation site.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Love have stent anchor extensions on both tubular member that extend beyond the graft ends as taught by Robinson and to make the stents out of nitinol as taught by Pinchuk in order to better anchor the graft to the stents and implant to the vessel.

Claims 4, 5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love in view of Robinson and Pinchuk and further in view of United States Patent Fearnot et al 6,358,284 B1.

The combination of Love in view of Robinson and Pinchuk discloses the invention substantially as claimed being disclosed above. However, the combination does not disclose that the tissue graft comprises multiple layers of submucosa.

Fearnot teaches the use of tubular grafts comprising layers of submucosa sheets in the same field of endeavor for the purpose of providing enhanced repair of damaged or diseased host tissues.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot with the stent graft of Love as modified by Robinson and Pinchuk in order to provide enhanced repair of damaged or diseased host tissues.

Claims 1, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk United States Patent 5,628,788 in view of Fearnot et al United States Patent 6,358,284 B1 and further in view of Love United States Patent 5,865,723.

Pinchuk discloses the invention substantially as claimed being a double-layered stent graft wherein the inner stent is smaller than the outer stent and the ends of each layer are at least coincident as seen in figures 3-9. However, Pinchuk does not disclose that the graft comprises multiple layers of tissues or that they are held together solely by compressive forces.

Fearnot teaches the use of tubular grafts comprising layers of submucosa tissue sheets in the same field of endeavor for the purpose of providing enhanced repair of damaged or diseased host tissues.

Love teaches use of an implant comprising a graft compressed between a pair of stents that retains its positioning during and after implantation without adhesives or sutures, solely by compressive forces in the same field of endeavor for the purpose of eliminating the use of adhesives and their possible side effects.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot with the double layered stent graft of Pinchuk and to eliminate the use of adhesives in light of compressive forces as taught by Love in order to provide enhanced repair of diseased host tissues and better anchoring and expansion and to better anchor the implant to the vessel without the use of adhesives that could cause undesired side effects.

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

/Christopher D Prone/

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/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738